Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
13232WO/ko		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/003400	31.03.2004	02.04.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant		
BIOPLANTA ARZNEIMITTEL GMBH		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 9 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))
      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/003400

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 2-7 as originally filed/furnished

pages* 1 received by this Authority on 01.02.2005 with letter of 01.02.2005

pages* _____ received by this Authority on _____

☒ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 1-12 received by this Authority on 01.02.2005 with letter of 01.02.2005

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/003400

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims		YES
	Claims	1-12	NO
Inventive step (IS)	Claims		YES
	Claims	1-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Subject matter of the claims:

Claims 1-6 (see earlier product claims 1-6) redrafted as second non-medicinal use claims:

Claim 1: the use of a polyphenolic plant extract ***for delaying the release of the contents of gelatin capsules***, one of the ingredients contained in the capsule being the polyphenolic plant extract;

claim 2: the capsule contents: a polyphenolic plant extract and a liquid carrier substance that is not miscible with water;

claim 3: a plant extract, for example from *Camellia sinensis, Crataegus monogyna, Ginkgo biloba, Humulus lupulus* [...] *Vaccinium myrtillus* etc.;

claim 4: a liquid carrier substance that is not miscible with water: unsaturated oils (in particular with a high omega-3 fatty acid content);

claim 5: a liquid carrier substance that is not miscible with water: perilla seed oil, evening primrose seed oil [...] fish oil, borage oil, linseed oil;

/...

claim 6: further substances contained in the capsule: plant oils, beeswax, lecithin, neutral oil, hydrogenated fat, microdispersed silicon dioxide, sorbitan monooleate.

Claims 7-12 - method claims for "delaying release":

claim 7: the use ***for delaying the release of the contents of gelatin capsules***, a polyphenolic plant extract being introduced into the capsule contents.

For claims 8 to 11 see claims 2-5.
For claim 12 see claim 6.

In the present report, reference is made to the following documents:

D1: US 5 955 102 A (IBRAHIM NAGUI ET AL)
21 September 1999

discusses a **nutritional supplement** containing **docosahexanoic acid (DHA)**, lutein and **anthocyanosides** (column 1, lines 6-8):

- **docosahexanoic acid (DHA) and eicosapentaenoic acid (EPA)** are **omega-3 (.omega.3)-polyunsaturated fatty acids (PUFA)** which are naturally occurring in oils of marine origin (column 1, lines 11-13);
- **anthocyanosides** are a group of red to blue plant pigments which occur as condensed products (glycosides) of anthocyanins or anthocyanidins combined with a sugar, such as glucose, arabinose

/...

or galactose for example; blueberries or whortleberries contain a variety of anthocyanosins, including cyanidine, malvidine, delphynidine, petunidine and peonidiene; they are similar in structure and function to bioflavonoids (column 1, lines 39-46).

The nutritional supplement is preferably provided as a capsule and includes a **liquid** or dry **inner filling** and an outer shell; in a **preferred embodiment**, the **inner filling** is **a liquid mixture which is contained within a gelatin capsule**, for example a "softgel" type of capsule (column 2, lines 31-35).

The inner filling includes DHA, lutein and at least one anthocyanoside. "DHA" refers to the free acid form of **docosahexaenoic acid**, not the phospholipid form or the ester form. One naturally occurring source of DHA is **fish oil** (column 2, lines 36-39).

Any source of anthocyanosides can be used, preferably an extract of bilberry (*Vaccinium myrtillus*, a small perennial scrub that is native to northern Europe and Asia).

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

D2: EP 0 502 766 A (INST RECH BIOLOG SA)
9 September 1992

relates to a new dietary composition supplying cerebral phopholipids, alone or in combination with animal oils (rich in unsaturated fatty acids of the omega-3 series) (page 2, lines 1-5);

the **oils of cold-water sea fish** (cod, halibut, herring...) are rich in **DHA** (page 2, lines 37-38);

in addition, said dietary compositions can contain **anthocyanoside** as **in whortleberry extract** (page 2, lines 53-54); the dietary preparation is administered in the form of 2 to 4 capsules (page 3, lines 30).

D3: GB 1 011 265 A (RIKEN VITAMIN OIL CO LTD; TAKEDA CHEMICAL INDUSTRIES LTD)
24 November 1965 (1965-11-24).

claim 1: a **process for the preparation of a medicinal agent** for the treatment of hypercholesterolemia, said agent **consisting of the oils of marine animals** and **an antioxidant** being added **to the oils** (see also page 2, column 1, lines 5-7 and column 2, lines 95-102);

claim 3: the **antioxidant is *inter alia* propyl gallate**, butylated hydroxyanisole, butylated hydroxytoluene, or tocopherol;

claim 7: the **medicinal agent is in the form of a capsule**,...

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

D4: PATENT ABSTRACTS OF JAPAN, vol. 0145, no. 62 (C-0788), 13 December 1990 (1990-12-13)
& JP 2 243622 A (NIPPON OIL &; FATS CO LTD), 27 September 1990 (1990-09-27)

A fat and oil composition consisting of **(1) oil** and fat containing alpha linolenic acid, eicosapentaenic acid and/or docosahexaenic acid **and (2) crude catechin extracted from tea leaf** (*Tea shinensis*); alpha-linolenic acid is found in (for example) linseed oil, eicosapentaenic acid and docosahexaenic acid - for example in **fish oil**; the composition is administered orally in the form of **capsules**.

D5: CN 1 279 072 A (GAO LIN)
10 January 2001 (2001-01-10)

A medicinal agent in the form of a **capsule** containing, *inter alia*, nucleic acid powder, soya bean lecithin powder, **tea polyphenols**, [...], linolenic acid fish oil, sesame oil, etc.

D6: EP0573777 A 19931215 (IdB Holding S.p.A.)
15 February 1993

describes pharmaceutical oral preparations containing a high proportion of **anthocyaneosides (HCA)** as an active principle; the fruits of many plants, such as ***Vaccinium myrtillus***, ***Ribes nigrum***, ***Vitis vinifera*** and *Sambucus nigra*, are starting materials for the preparation of anthocyanosides.

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Novelty (i), inventive step (ii) and industrial applicability (iii) (PCT Article 33(1) to (4))

(i) and (ii):

With respect to the new use in a capsule of known substances, the wording of the claim does not disclose any technical features that clearly reflect said new use.

This notwithstanding, it is to be assumed that the property currently claimed is already inherent to the formulations known from the prior art.

Furthermore, the examples submitted to date do not provide convincing evidence in support of the new use.

No data has been submitted as evidence of the unexpected effect or, in relation thereto, of the intended new "delayed release from gelatin capsules" of the polyphenolic substances by comparison with existing formulations; in particular there is no data relating to the release of any contents from gelatin capsules.

According to the description (see page 7, lines 3-5), for example in the context of the "testing of the decay time in accordance with the 'European Pharmacopoeia'", mention is made of a "pre-storage decay time of 4 minutes". However, in so far as this gives no information concerning the composition of such a capsule, it is not meaningful for the purpose of comparison with the capsules of the prior art.

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Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Thus, at the present time neither the requirements for novelty nor those for inventive step appear to have been satisfied.